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U.S. Patent and Trademark Office Attn: Examiner T. Wessendorf Art Unit: 1639	(571) 273-8300	(571) 272-0812

FROM: Kate H. Murashige - Reg No. 29,959

**DATE:** February 27, 2007

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#### Comments:

ATTORNEY DOCKET:

388512010101

GROUP ART UNIT:

1639

**EXAMINER:** 

T. Wessendorf

SERIAL NO.:

10/678,414

FILING DATE: INVENTOR(S):

October 2, 2003 Lawrence M. KAUVAR, et al.

TITLE:

MULTIHUE LABELS

#### Papers attached:

Please find a copy of the response that was filed on October 13, 2006, along with a copy of the stamped receipt postcard showing it was received on October 16, 2006. Examiner Wessendorf does not have a copy of this response and we are merely supplying the attached copy for your file. Thank you.

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Inventor: Lawrence M. KAUVAR et al.

Application No.: 10/678,414 Title: MULTIHUE LABELS

Atty Docket No.: 388512010101

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Filing Date: October 2, 2003

Documents Filed:

Transmittal (1 page)
Fee Transmittal (1 page + duplicate)
Amendment Under 37 C.F.R. § 1.111 (7 pages)
Terminal Disclaimers (2 pages)

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Date: October 13, 2006

Inventor: Lawrence M. KAUVAR et al.

Application No.: 10/678,414 Title: MULTIHUE LABELS Atty Docket No.: 388512010101

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**Documents Filed:** 

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Date: October 13, 2006

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Application Number 10/678,414

Filting Date October 2, 2003

First Named Inventor Lawrence M, KAUVAR

Art Unit

FORM (to be used for all correspondence after initial fiting)  First Named Inventor  Art Unit 1639  Examiner Name T. Wessendorf  Total Number of Pages in This Submission 12 Attorney Docket Number 388512010101  FOR Transmittal Form (1 page + duplicate for fee processing)  Fee Attached  Drawing(s)  After Allowance Communication to TC (Appeals and Interferences  Amendment Under 37 CFR § 1.111  Petition  After Final  Provisional Application  After Final  Provisional Application  Aftidavitz/dectaration(s)  Extension of Time Request  Information Disclosure Statement  Reply to Missing Parts/ Incomplete Application  Customer No. 25225			Filing Date	October 2, 2003			
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Signature Kate & Williamsley	Cotte let M	unela	~=				
Printed name Kate H. Murashige	Printed name						
Date October 13, 2006 Reg. No. 29,959	October 13, 2006	•	Reg. No.	29,959			

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Box 1450, Alexandria, VA 22313-1450.	~
·	Signature: Kabenta Vindon (Roberta Vinson)
Dated; October 13, 2006	Signature: (Roberta Vinson)
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X Applicant claims small entity status. See 37 CFR 1.27	Art Unit	1639	·			
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Signature Lake to. Musely	Registration No. 29,95 (Attorney/Agent)	9 Telephone	(858) 720-5112			
Name (Print/Type) Kate H. Murashige		Date	October 3, 2006			

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FEE TRANSMITTAL For FY 2006		Filing Date		October 2, 2003				
		First Named Inv	entor	Lawrence M. KAUVAR				
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SUBMITTED BY	W . 14 3	<u> </u>		Registration No.	29,959	Telephone	(858) 720	-5112
Signature		Murael	<del>~~</del>	(Anomey/Agent)	20,000	Date	October 3	
Name (Print/Type)	Kate H. Murashig	e					<del></del>	·

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Dated: October 13, 2008

Signature: Kabanta Vunso

said Docket No.: 388512010101

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Lawrence M. KAUVAR, et al.

Application No.: 10/678,414

Filed: October 2, 2003

For: MULTIHUE LABELS

Confirmation No.: 9986

Art Unit: 1639

Examiner: Teresa D. Wessendorf

#### AMENDMENT UNDER 37 C.F.R. § 1.111

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:



This is in response to an Office Action herein, mailed 25 August 2006, time for response to which was set to expire 25 November 2006. Claims 43-47 and 50-51 were examined and rejected. Claims 48-49 were withdrawn from consideration, but would be rejoined if a generic claim were allowed. Careful consideration has been given to the grounds for rejection, and the following amendment and discussion are offered in response. Reconsideration is respectfully requested.

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Application No.: 10/678,414

Docket No.: 388512010101

#### CLAIM AMENDMENTS

#### 1-42. (canceled)

- 43. (currently amended): A particulate label which comprises
- (a) a particulate support having a diameter of no more than 100 nm to which particle is bound to at least three fluorophores, wherein each said fluorophore emits a detectable signal different distinguishable from that emitted by the others and wherein the magnitude ratio of intensities of each of said emitted signals provides a distinctive hue and wherein the magnitude of the signal emitted by each said fluorophore may be varied; and
- (b) wherein said particulate support is coupled to a reagent coupled to said particulate support.
- 44. (previously presented): The label of claim 43, wherein the particulate support is a latex bead.
- 45. (previously presented): The label of claim 43, wherein the reagent is an antibody or fragment thereof, a peptide generated from a cDNA library, a substance in a combinatorial chemistry library, or an oligonucleotide.
- 46. (previously presented): The label of claim 43, wherein the reagent is coupled to the particulate support by a covalent linkage.
- 47. (previously presented): The label of claim 46, wherein the covalent linkage is a disulfide or carboxamide linkage.
- 48. (withdrawn): The label of claim 43, wherein the reagent is linked to the particulate support by a non-covalent linkage.

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49. (withdrawn): The label of claim 48, wherein the non-covalent linkage is an epitope/antibody linkage, or

a histidine/chelated NI linkage, or comprises an agar layer in which reagent is trapped.

- 50. (currently amended): A spatially defined arrangement of a multiplicity of particulate different labels of claim 43, wherein each label is characterized by a different hue distinguishable from the hue of different labels, and each different particulate support is bound to a different reagent.
- 51. (previously presented): The arrangement of claim 50, which is displayed on a surface to permit determination of the spatial position of said labels.



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Docket No.: 388512010101

#### REMARKS

Claim 43 has been amended in response to the rejection under 35 U.S.C. § 112, paragraph two. Support for this amendment is found, for example, on page 10 of the specification, which discusses the signals in terms of their intensities. The requirement that the signals be distinguishable is clear in that the various colors emitted can be distinguished from each other, as described in the paragraph on page 10, beginning at line 11 and Figure 2 referred to therein. Support for the ratio of intensities is also found in this paragraph. See, e.g., line 17 on page 10. The remainder of the amendment is editorial. Claim 50 has been similarly clarified. Accordingly, no new matter has been added. Entry of the amendment is respectfully requested.

Applicants have found that it is possible to couple three or more fluorophores to a very small particle having a diameter of no more than 100 nm. To applicants' knowledge, this is the first disclosure of such small and efficient particulate labels.

#### Double-Patenting

Applicants believe the double-patenting rejection is improperly based on consideration of the specifications of the cited documents rather than the claims *per se* as is the appropriate referent for such assessment. However, in order to expedite prosecution, terminal disclaimers with respect to U.S. 6,492,125 and U.S. 6,642,062 are enclosed.

#### The Rejections Under 35 U.S.C. § 112, Paragraph Two

All claims were rejected under this statutory section. Claim 43 has been extensively amended in response. By separating the particulate support bearing the fluorophores from the reagent that is coupled thereto into separate paragraphs, it is believed that the claim is clarified. The

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particulate label contains both the particulate support and the reagent. The term "magnitude" has been replaced by "intensity" which is believed clear, and the term "different" is replaced by the functionally meaningful "distinguishable." It is believed, therefore, that the objections of the Office have been met.

Claim 50 is asserted to be a duplicate of claim 43. This basis for rejection is not understood. Claim 43 requires only a single particulate label; claim 50 requires an arrangement of a multiplicity of different particulate labels and they must be spatially arranged so that they can be separately identified.

Similarly, claim 51 further limits claim 50 because the spatial arrangement must be on a surface – not within a three-dimensional volume.

Accordingly, this basis for rejection may properly be withdrawn.

#### The Rejection Under 35 U.S.C. § 102

All claims were rejected as assertedly anticipated by Chee, et al., U.S. patent 7,033,754.

Applicants believe the rejection is in error for the following reason.

The present application is a continuation of U.S. Serial No. 09/146,984 filed

3 September 1998 – i.e., U.S. patent 6,642,062 cited by the Office. Therefore, the only § 102(e)

date that can be asserted for Chee, et al., is that of provisional application number 60/090,473 filed

24 June 1998. All of the remaining documents from which Chee, et al., claim priority are later than
the filing date of the parent herein. It is unclear from the present record whether the provisional
application that might properly be cited anticipates the present invention. However, according to
the copy of the application available on PAIR, it appears that microspheres as small as 100 nm are
not disclosed. Page 10, beginning at line 30, describes bead sizes from 500 nm to millimeter size

Docket No.: 388512010101

and a preferred lower dimension of 200 nm. What appears to be the corresponding portion in the issued patent, at column 10, specifies 100 nm/ml, unlike the provisional which specifies 500 nm/ml.

Applicants would appreciate an analysis of provisional 60/090,473 which might properly be cited against the present application as opposed to the issued parent which, unless supported by the provisional, is not. Since the provisional application can be read and printed only one page at a time on PAIR, a copy of this application would be helpful in evaluating its disclosure.

In that regard, it would be helpful to have portions of the text more precisely identified than what appears to be approximately 20 pages of specification (column 9-column 32).

In view of the apparent failure of the provisional application to anticipate, this basis for rejection may properly be withdrawn.

#### The Rejection Under 35 U.S.C. § 103

Respectfully, as this rejection requires the combination of Chee, which is not properly cited, with additional documents, this rejection may be withdrawn for the reasons set forth above.

#### Conclusion

Terminal disclaimers have been submitted to overcome the double-patenting rejection. The claims have been amended to overcome the rejection under 35 U.S.C. § 112, paragraph two. It does not appear that the earliest priority document of the primary reference, Chee, discloses the particulate labels of the invention. Thus, it is believed all grounds for rejection are overcome and passage of pending claims 43-47 and 50-51 to issue, along with claims 48-49 which may be rejoined, is respectfully requested.

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Docket No.: 388512010101

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to <u>Deposit</u>

Account No. 03-1952 referencing <u>docket No. 388512010101</u>.

Respectfully submitted,

Dated:

October 13, 2006

 $\mathbf{R}\mathbf{v}$ 

Kate H. Murashige Registration No. 29,959 MORRISON & FOERSTER LLP

12531 High Bluff Drive

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid QMB control number. Docket Number (Optional) TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT 388512010101 Lawrence M. KAUVAR et al. In re Application of: 10/678,414 Application No.: October 2, 2003 Filed: MULTIHUE LABELS For. 100 percent interest in the Trellis Bioscience, Inc. instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the Instant application which would extend beyond the expiration date of the full statutory term of prior patent No. as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later. expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutority disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all craims canceled by a reexamination certificate; is relssued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. Check either box 1 or 2 below, if appropriate. For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are purishable by fine or Imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. The undersigned is an attorney or agent of record. Reg. No. October 13, 2006 Date Kate H. Murashige Typed or printed name (858) 720-5112 Telephone Number x Terminal disclaimer fee under 37 CFR 1.20(d) is included. \*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information units it displays a valid OMB control numb Docket Number (Optional) TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT 388512010101 Lawrence M. KAUVAR et al. In re Application of: 10/678,414 Application No.: October 2, 2003 Filed: MULTIHUE LABELS For: percent interest in the 100 Trellis Bioscience, Inc. instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent No. as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above discialmer, the owner does not discialm the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patient, "as the term of said prior patent is presently shortened by any terminal discialmer," in the event that said prior patent expires for fallure to pay a maintanance fee: is held unenforceable: is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. Check either box 1 or 2 below, if appropriate, For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. The undersigned is an attorney or agent of record. Reg. No. October 13, 2006 Date Kate H. Murashige Typed or printed name (858) 720-5112 Telephone Number Terminal disclaimer fee under 37 CFR 1.20(d) is included. 'Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.